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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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John A. Dyjach

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EXAMINER

SMITH, TERRI L

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

JP

Office Action Summary	Application No.	Applicant(s)	
	10/728,124	DYJACH ET AL.	
	Examiner	Art Unit	
	Terri L. Smith	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8-8-07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08 August 2007 has been entered.

Response to Arguments

2. Applicant's arguments filed on 08 August 2007 with respect to claims 1–28 have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.

3. Additionally, Applicant's arguments filed on 08 August 2007 have been fully considered but they are not persuasive. As a result, the prior art of Oung et al., U.S. Patent 7,079,888, Levine, U.S. Patent 6,865,414 and Jensen, U.S. Patent 6,941,332 will be used again in this Office Action.

In response to Applicant's arguments stating: The mere fact that references *can* be combined or modified, however, does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. MPEP 2403.1; *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). Applicant does not believe that anything in the prior art of record suggests the desirability of using interval-based filtering of ectopic events in the computation of heart rate variability metrics. Heart rate variability metrics are especially susceptible to corruption by ectopic beats, and it is ectopic beats with outlying intervals that are especially damaging in that regard. No recognition of the problem solved by Applicant's claimed

subject matter has been shown to exist in the prior art (see **REMARKS** page 7), the Examiner respectfully disagrees.

The Examiner recognizes that references cannot be arbitrarily combined and that there must be some reason why one skilled in the art would be motivated to make the proposed combination of primary and secondary references. *In re NomiyaI*, 184 USPQ 607 (CCPA 1975). The test for combining references is what the combination of disclosures taken, as a whole would suggest to one of ordinary skill in the art. *In re McLaughlin*, 170 USPQ 209 (CCPA). References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. *In re Bozek*, 163 USPQ 545 (CCPA) 1969.

In this case, Levine (U.S. Patent 6,865,414) discloses: This invention relates generally to a programmable cardiac stimulation device for the purpose of differentiating between normal sinus events and ectopic beats (e.g., column 1, lines 9–11; ABSTRACT, lines 1–3; FIGS. 3–7). And, Oung et al. disclose: The method in accordance with the present invention allows spectral analysis ... to be applied to time-varying biological data such as heart rate variability ... (e.g., column 3, lines 63–66) and Electrical activity in the heart can affect heart rate variability analysis by causing abnormal heart beat interval wave formation. ... Thus, these erroneous signals need to be removed before performing the spectral analysis on the RR-interval tachogram or instantaneous heart rate waveform. Using interpolation, these disturbances or ectopics are removed to provide the corrected heart rate signal, as described below. (e.g., column 5, lines 34–36 and 38–43). In these stated purposes of the Levine and Oung et al. inventions it is readily apparent that the combination of the two inventions recognizes the problem solved by Applicant's claimed subject matter as Applicant stated in the aforementioned arguments.

In that normal sinus events and ectopic beats are based measurements of intervals, and that they are differentiated, and that the device has filtering capabilities (e.g., column 7, line 28), and ectopics are removed to provide corrected heart rate signal in conjunction with heart rate variability analysis, it is readily apparent that the combination of the inventions of Levine and Oung et al. suggest the desirability of using interval-based filtering for ectopic events in the computation of heart rate variability metrics.

It is further noted that Applicant's specification discloses: "Regardless of the particular heart rate variability metric, however, it is desirable to exclude from the BB interval signal those BB intervals which are due to ectopic cardiac activity such as PVC's. The present invention relates to a BB interval filtering technique for removing non-sinus rhythm events from a BB interval series used for heart rate variability analysis" (on page 6) and "For purposes of heart rate variability analysis, it is therefore desirable to exclude those BB intervals from a BB time series which are due to ectopic cardiac activity and are not the result of a normally conducted heart beat. It is with this problem that the present invention is primarily concerned" (page 2) and "One way to derive a BB interval signal representing heart rate variability during a sinus rhythm is to remove ectopic beats with an event-based technique ... BB intervals adjacent to the PVC can then be removed from the BB interval series used for heart rate variability calculations (or changed to interpolated values)" (page 9). It is the Examiner's position that these teachings in the Applicant's specification are obviously realized by the combined teachings of Levine and Oung et al.

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Regarding Applicant's argument pertaining to establishing *prima facie* obviousness of a claimed invention on page 8 of the **REMARKS**, Examiner applies the same argument stated herein above in response to Applicant's argument regarding the combining of references.

Claim Rejections - 35 USC § 102/103

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the Applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the Applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 4, 5, 6, 11, 12, 13, 15, 18, 19, 20, 25, 26 and 27 are rejected under 35 U.S.C. 102(e) as anticipated by Oung et al., U.S. Patent 7,079,888 or, in the alternative, under 35 U.S.C. 103(a) as obvious over Oung et al., U.S. Patent 7,079,888.

8. Regarding claims 1, 4, 5, 6, 11, 12, 13, 15, 18, 19, 20, 25, 26 and 27, Oung et al. disclose sensing electrical activity in a cardiac chamber (e.g., Figure 1, element 101, EKG source) and generating a chamber sense signal (e.g., column 5, lines 22–24, where it is the Examiner's position that "produce a pulse train" represents generating a chamber sense signal; lines 55–67); measuring time intervals (e.g., column 5, lines 17–19 and 24–28); filtering BB intervals (e.g., column 5, lines 21–42; column 14, line 10); updating a plurality of preceding BB intervals (column 6, lines 1–15); and, computing heart rate variability metrics (e.g., column 6, lines 16–48; column 8, lines 1–33). It is noted that it is unclear if the implantable medical device is being positively recited; therefore, Examiner used the external device of Oung et al. as cited above as pertinent prior art that discloses the claimed limitations as set forth in the present invention.

9. In the alternative, regarding claim 1, Oung et al. state in column 11, lines 19–20 that the device can be applied in various environments, but not explicitly in an IMD. However, it is well known in the art for an IMD to be operated remotely to ensure reliable, precise and safe cardiac therapy on demand. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Oung et al. to include an IMD

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and for the IMD to be operated remotely to ensure reliable, precise and safe cardiac therapy on demand.

10. Claims 1–8, 10–22 and 24–28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine, U.S. Patent 6,865,414 and in view of Oung et al., U.S. Patent 7,079,888.

11. Regarding claims 1 and 15, Levine discloses sensing electrical activity in a cardiac chamber and generating a chamber sense signal (e.g., column 5, lines 19–20; column 6, lines 53–59);

measuring time intervals (e.g., Figs. 3–7; column 11, lines 7–9; column 17, lines 14–16);

filtering BB intervals (e.g., column 12, line 56–column 13, line 5; column 13, line 64–column 14, line 1–4 and lines 11–18; column 17, lines 9–12).

updating a plurality of preceding BB intervals (e.g., FIGS. 3–5; column 13, lines 28–34 and 45–63. As cited immediately herein, it is further noted that the other cited figures (flowcharts) and their respective descriptions detail how the updating limitation is also executed.).

Levine does not disclose computing a heart rate variability metric. However, Oung et al. disclose computing a heart rate variability metric (e.g., Figures 1 and 3; column 6, lines 16–48; column 8, lines 1–33) to quickly and accurately obtain heart rate variability metrics to better assist medical personnel in diagnosing and treating various cardiac conditions and provide a system that is less sensitive to errors that result during the monitoring time period.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Levine to include computing a heart rate variability metric, as taught by Oung et al. to quickly and accurately obtain heart rate variability

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metrics to better assist medical personnel in diagnosing and treating various cardiac conditions and provide a system that is less sensitive to errors that result during the monitoring time period.

12. With respect to claims 2 –6, 14, 16 –20 and 28, Levine discloses a statistic is a median value (claims 2 and 16), and a weighted average (claims 3 and 17) of a plurality of preceding BB intervals (e.g., Fig. 5; column 12, lines 42–64);

chamber senses are ventricular senses (e.g., Figs. 2–3 and 7; column 5, line 27; column 10, lines 43–46; column 15, lines 8–13) and BB intervals are RR intervals (claims 4 and 18) (e.g., Figs. 3–5; column 8, lines 7–13; column 11, lines 33–36);

a specified threshold value is a specified number (claims 5 and 19) (e.g., Fig. 3) and a specified percentage of a computed statistic (claims 6 and 20) (e.g., Fig. 4; column 11–column 12, lines 1–10);

maintaining a count of the number of detected ectopic beats (claims 14 and 28) (e.g., column 1, lines 17–19).

13. Regarding claims 7, 8, 21 and 22, Levine discloses evaluating a present BB interval and excluding a present BB interval as an ectopic interval (claims 7 and 21) and removing the oldest interval and storing a present BB interval (claims 8 and 22) (e.g., Figs. 3–7 where evaluating is initiated at steps 314, 320, 324, 410, 512, 516, 518, 714, 720, 724; column 11–column 16, lines 1–16).

However, Levine does not disclose expressly the claimed limitations of a first-in-first-out **buffer**. It would have been an obvious matter of engineering design choice to one of ordinary skill in the art at the time the invention was made to modify the microcontroller and its associated circuitry (which perform the limitations of the buffer in the claimed invention) as

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taught by Levine, to have a first-in-first-out buffer to perform the claimed limitations of the invention as described herein above, because Applicant has not disclosed that a first-in-first-out buffer and its uses thereof provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the microcontroller and its associated circuitry as taught by Levine, because it provides a history record of ectopic events, distinguished by sensing thresholds and timing intervals, giving a valuable diagnostic tool to the physician in optimizing rhythm management therapy.

Therefore, it would have been an obvious matter of engineering design choice to modify the microcontroller and its associated circuitry to obtain the invention as specified in the claim(s).

14. With respect to claims 11–13 and 25–27, Levine discloses the essential features of the claimed invention as described above except for a heart rate variability metric is a parameter computed by time-domain filtering (claims 11 and 25), frequency domain analysis (claims 12 and 26) and a statistical surrogate of a frequency component (claims 13 and 27).

However, Oung et al. disclose a heart rate variability metric is a parameter computed by time-domain filtering, frequency domain analysis and a statistical surrogate of a frequency component (e.g., column 6, lines 16–48; column 8, lines 1–33) to quickly and accurately obtain heart rate variability metrics to better assist medical personnel in diagnosing and treating various cardiac conditions.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Levine to include a heart rate variability

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metric is a parameter computed by time-domain filtering, frequency domain analysis and a statistical surrogate of a frequency component, as taught by Oung et al. to quickly and accurately obtain heart rate variability metrics to better assist medical personnel in diagnosing and treating various cardiac conditions.

15. Regarding claims 10 and 24, Levine discloses a lowest numerical value and a lowest numerical setting (e.g., column 12, lines 31–37 and 46–49), but not that the number N is three. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include that the number N is three, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). (See MPEP 2144.05).

16. Claims 9 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine and Oung et al. as applied to claims 1 and 15 above, and further in view of Jensen, U.S. Patent 6,941,332.

17. Levine discloses the essential features of the claimed invention as described above except for computing a median value and excluding a present BB interval ... greater or less than a computed median value.

However, Jensen discloses computing a median value and excluding a present BB interval ... greater or less than a computed median value (e.g., FIGS. 3–22; ABSTRACT, lines 1–18; column 4, lines 12–34; column 5, lines 15–33 and 39–49) to provide efficient and rapid filtering using computational mechanisms to ensure optimum performance of the implantable medical device.

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Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Levine and Oung et al. to include computing a median value and excluding a present BB interval ... greater or less than a computed median value, as taught by Jensen to provide efficient and rapid filtering using computational mechanisms to ensure optimum performance of the implantable medical device.

Conclusion


18. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is (571) 272-7146. The Examiner can normally be reached Monday–Friday between 7:30 a.m. - 4:30 p.m..

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


TLS

August 24, 2007

24 August 2007
GEORGE R. EVANISKO
PRIMARY EXAMINER*8/22/7*